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CATHETER DESIGN, VALIDATION, AND PRESENTATION USING CATHWORKS

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Abstract

Vascular interventional catheterization is becoming more and more popular for diagnosing and treating vascular diseases. This less invasive vascular procedure can significantly improve the quality of vascular disease treatment and reduce the health care cost and patient discomfort as well as the time of convalescence. Developing a novel device for interventional vascular procedures is a challenging task for the medical society. The aim of this work is to evolve the emerging technologies in engineering, computing, and medicine into product systems to improve the efficiency of a new catheter design, validation, and presentation. CathWorks, a CAD-integrated and feature-based prototype system for prototyping novel catheterization devices is described in this paper. CathWorks can be used to design catheters with reference to the built-in knowledge of variational vascular models. The designed catheters can be verified with CathWorks using an FEM based and computerized simulation. A comprehensive database is developed with CathWorks to support a multimedia presentation of catheter devices.

Key Words

Catheterization, prototyping, medical simulation, parametric modelling

1. Introduction

Catheterization, the less invasive surgery for vascular diseases, provides effective and quality service in significantly reducing patient discomfort, hospital stay, and medical cost. It often requires the ability to enter the vasculature through very small incisions and to maneuver therapeutic or diagnostic devices to the target lesion in a human body. With the smallest possible circular cross-sections, catheters are the most important device widely used in interventional procedures. More than any other type of interventional device, catheters are extremely diverse in shape and specific features [1]. Thousands of type of catheters manufactured by various companies are available in the market, while each year a large number of innovative new catheters are introduced worldwide. Each catheter is designed for its own purpose and is distinct from others with its own characteristics and configuration. Managing huge numbers of catheter devices in a CathLab is increasingly a tedious task for catheterization professionals. Surgeons often use their personnel preference and prior experience in selecting the devices for their catheterization procedures. Standard devices are designed for averages. Human beings, however, are very individualized. Selection of a specified catheter from their device base for a particular use can sometimes become an error-prone task. Incorrect selection and subsequent misuse of disposable catheter devices, not only leads to an increase in the patient's medical cost, but also can potentially develop inconsistencies in the performing characteristics of those devices. In the worse case, such inconsistencies can damage the vascular wall tissue.

In order to levitate the quality of medical care and meet the challenge of complicated catheterization practices, surgeons and engineers are constantly seeking innovative use of catheterization devices and novel catheter designs. This is largely due to the different disease situations and the variability of vascular anatomies of individual patients. For instance, the great variability in the origin and proximal segment of the right coronary artery (RCA) frequently poses problems for coaxial guiding catheter cannulation [2]. Optimal use or design of catheter devices is, therefore, always a challenging task for both surgeons and engineers in the catheterization community. However, lacking of a realistic design environment of accurate human vasculature and interactive computerized tools makes the traditional design process inflexible and less efficient.

To demonstrate the concept of a new device design, manual and destructive testing is typically used in the current manufacturing line. Traditional approaches, however, face difficulties to test the overall functional responsibility of catheters during the design phase due to their complexities in structure and various material properties. For example, the necessary balance between controllability and flexibility of the catheter needed to negotiate safely and effectively the circuitous paths of the body's inner core is one of the major considerations for the device design. How to facilitate the testing and validation of new properties for the newly designed catheter with computer simulation is of practical importance.

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We have been developing simulation and design technology for mechanical prototyping of new catheterization devices to meet the challenge of complicated cathetherization practices. CathWorks, a CAD-integrated and feature-based system, has been developed to evolve the emerging technologies in engineering, computing, and medicine into product systems for novel catheter development. CathWorks consists of three modules: CathPresenter is a graphics-enhanced and comprehensive package for catheter information presentation; CathDesigner is an interactive design package for innovative catheter designing; and CathValidator is a Finite Element Method (FEM) based verification package for efficient evaluation of the catheter device.

2. Catheter Presentation

With a lot of emphasis placed on the ease of use, CathPresenter is able to provide very comprehensive information for the catheterization device. The user-interface (UI) of the CathPresenter is shown in Fig. 1. It has the following parts:

- Product Line
- Comparative Information
- Training
- Searching
- Latest Technology

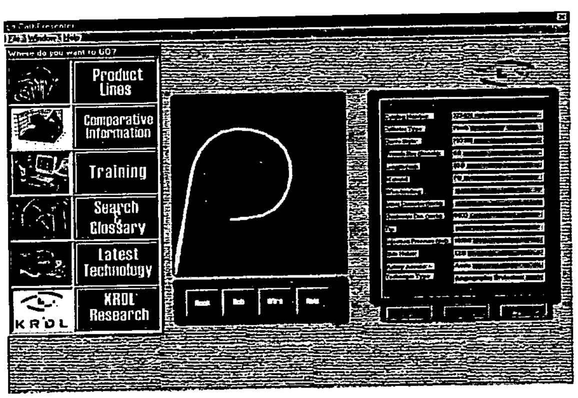

Figure 1. The user interface of the CathPresenter.

2.1 Comprehensive and Intelligent Information Provider

The product line collects over one thousand catheters available on the markets. For each catheter, users can retrieve information such as catalogue number, French size, length, maximal guide-wire diameter, side-holes, flow rate, contrast injection pressure, wire-braiding, material properties, and so on. The database behind the package is able to produce comparative service for products from different types, different manufacturers. Users can utilize the search engine (Fig. 2) to obtain catheter information for a particular product, or for products related to a specific topic such as anatomy, catheterization technique, and so on.

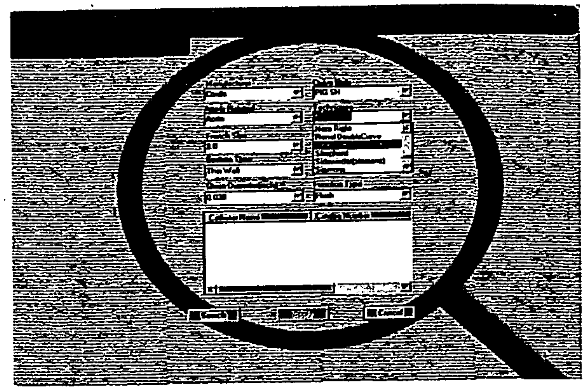

Figure 2. The search engine for information retrieval.

2.2 Graphics-enhanced Presentation Tool

CathPresenter is powered by the advanced computer graphics, imaging and simulation technologies. The detailed features of a catheter product are graphically presented with the system. To best illustrate the characteristics of a catheter, in the training sub-module, users can also visualize the relevant anatomical information. Furthermore, users can insert a selected catheter and navigate it inside the human vasculature to access a target artery. This helps to gain hand-on experience of the catheterization procedure (Fig. 3).

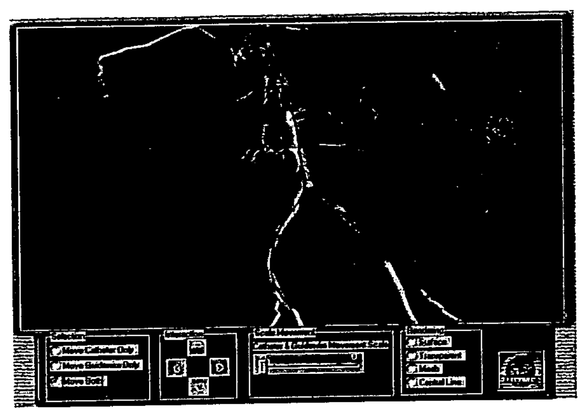

Figure 3. Navigating a catheter inside vasculature.

3. Catheter Design

3.1 Feature-based Catheter Design

Today, CAD tools are widely used in manufacturing, architecture, and engineering applications. Conventional CAD systems are, however, unable to properly address the issues of catheterization device design. Such CAD systems are typically for general design purposes with no or little direct medical knowledge built-in for the catheter designs.

The construction of catheter is rather unique in terms of functionality and geometry as well as material. Generally, a catheter is composed of several segments and the hook shape plays a central role in accessing a target artery. The shaft of the catheter is usually straight over most of its length. To achieve stiffness and torque control of

the catheter shaft, stainless steel or nylon braiding in the middle layer of the body is used to back-up catheter insertion. The catheter tip is its most distal segment that may have single or multiple side holes (through, blind, or spiral styles). The presence of side holes allows for increased contrast delivery with less tendency for catheter recoil. Some catheter tip designs may incorporate a soft tip. The hub of the catheter is bonded to the shaft and must have a strong, airtight seal. Catheter specifications may also be imprinted on the sleeve of the hub. Naturally, a feature-based modelling approach is most suitable for catheter building. In CathDesigner, typical feature operations include shape sweeping, extruding, holing, braiding, shelling, hub construction, and so on. CathDesigner is built upon the SolidWorks modelling tool on Intel PC and Window NT as a set of add-ins in the form of dynamic link libraries using SolidWorks API and Visual C++ programming.

3.2 Parametric Catheter Modelling

In CathDesigner, all catheterization devices are modelled parametrically [3]. This is realized by standardizing the devices into various categories and characterizing them by a number of salient parameters such as length, size, material properties, and so on. Device structure is described by its backbone geometry defined by a sequence of rod points. The curvature of the backbone can be changed by interactive modification during design or by deformation during verification testing. The subdivision of the rods along the backbone coincides with the generation of the finite elements. The catheters are modelled hierarchically in four parts (tip, hook, shaft, and hub) and each of the parts is designed in a layered structure. The parameter change and modification in material property, geometric dimension, and hierarchical structure result in different variant models of catheters.

The feature-based and parametrical modelling technique allows CathDesigner to capture the similarities of the catheterization devices. Doing so, users need to address only some predefined sets of values to create a device that conforms to the respective norms. For the parametrically designed products, not only device variational changes for design and simulation become possible, but also the optimized determination of the parameter values considering given constraints can be performed.

3.3 Shape Library-based Catheter Design

Curve shape is the central part of a catheterization device. Great effort has been made by various surgeons and engineers to design catheter shape in order to achieve optimized performance of catheterization. Such knowledge is valuable. A shape library is developed in CathDesigner. This catheter library comprises a list of curve shapes for commonly used guiding and diagnostic catheters [1]. Users can select one of the curve shapes from the library and then configure the catheter by entering the basic parameters such as length, French size of external and internal diameters for catheter. Next, for hole configuration, users need to specify the hole style (through, blind, or spiral), number, size, location, and so on. Wire braiding parameters and material properties are also required to key-in with the dialogue box. Fig. 4 shows the user interface (UI) for catheter construction. This UI is shared by other catheter modelling methods that will be described later.

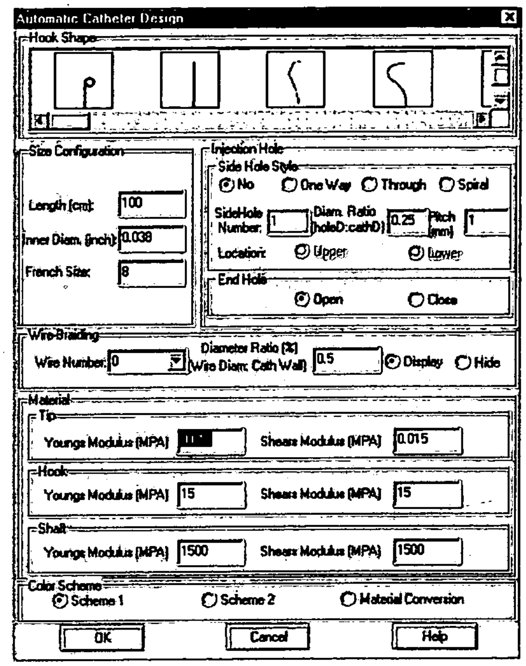

Figure 4. The user interface for catheter construction.

3.4 Model-based Catheter Design

From segmented medical images, a central line model of the vasculature can be constructed. This model is represented in hierarchical structure consisting of vessel topology (parent-child relationship), vessel geometry (coordinates and radii), and vessel material property. The 3-D model of the vessels is then reconstructed based on the central line geometry and a visual smoothness is achieved by employing operations such as sweeping and blending. A variational modelling approach is implemented for vasculature segments. The advantage of this method is that it provides flexibility in changing the 3-D structure to allow variational analysis of the individual vascular anatomy.

Based on the variational vascular model, users can select vessel segments and define a cross-sectional plane to section the model. A drawing sketch can then be created from the cross-section for free drafting of the curved hook shape with reference to the vascular model. Users can interactively modify the curve shape at this stage to obtain a satisfactory result. This method creates a planar curve shape based on the vasculature model. When a "new design" of the curve shape is generated, CathDesigner is ready to construct the catheter with a given catheter configuration. By selecting the "new design" for curve shape, users can activate the same user interface (Fig. 4) to set various parameters and start building the catheter. Fig. 5 illustrates the procedure for model-based catheter design. The coronary vascular model is shown in Fig. 5a. Fig. 5b illustrates the same model that has a narrowed

right coronary artery segment created by a variational modelling technique. Fig. 5c is a cross-sectional view and a hook curve is drawn on the cross-sectional sketch. Fig. 5d illustrates the constructed catheter with the created curve shape and selected catheter configuration (the shaft length is shortened for easy viewing).

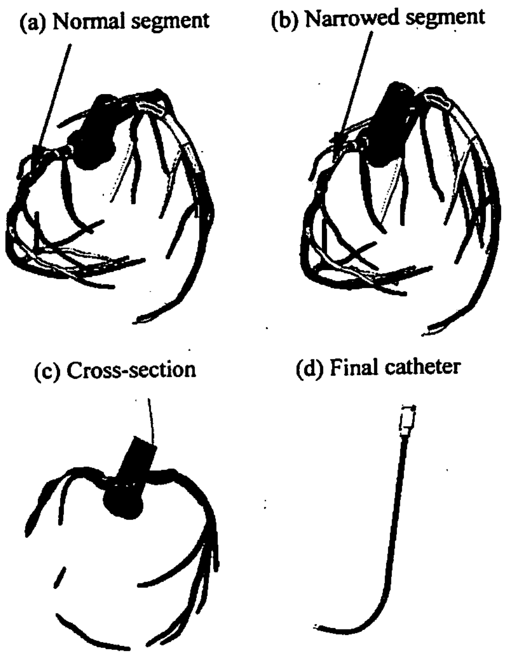

Figure 5. Vascular model-based catheter design. (a) Normal segment. (b) Narrowed segment. (c) Cross-section. (d) Final catheter.

3.5 3-D Navigation-based Catheter Design

As mentioned earlier, the different disease situations and great variability in vascular anatomies of individual patients often pose difficulties to surgeons when identifying a match or candidate catheter device for diagnostic or therapeutic catheterization. In such cases, computer simulation may help to create a customized catheter better fitted to the particular patient. This can be realized by performing virtual catheter navigation inside the human vascular network. An incremental FEM engine is developed to simulate the virtual catheter and guide-wire navigation within the vascular structure [4-7]. This FEM engine embedded in the CathDesigner is able to provide a real-time simulation of catheter/guide-wire interaction with blood vessels. Currently, the human primary vasculature, cardiac, and other secondary or tertiary networks are built in the system as a virtual patient for the purpose of navigation. The primary arterial vasculature is constructed from the VHD^{T}M data. The secondary and tertiary network is constructed from other scanned human vascular data, and the cardiac vessel network comes from a professional steel model using a computerized measuring method. The vascular anatomy is represented by the central lines and corresponding radii of the vessels [8]. The virtual catheter consists of a sequence of rod elements with variable material property. It can be manipulated via rotating and advancing/retracting to reach a desired position inside the blood vessels (Fig. 6a). During the navigation process, the catheter will negotiate with the vessel wall to generate a numerical path that is formed by the FEM calculation [4]. Of course, users are able to change the material property of the virtual catheter in order to achieve an optimized solution. When the navigation of the virtual catheter is complete, the 3-D numerical path is ready for building a real catheter by selecting the proper catheter configuration (Fig. 6b). This method usually creates 3-D curved (non-planar) catheter hooks.

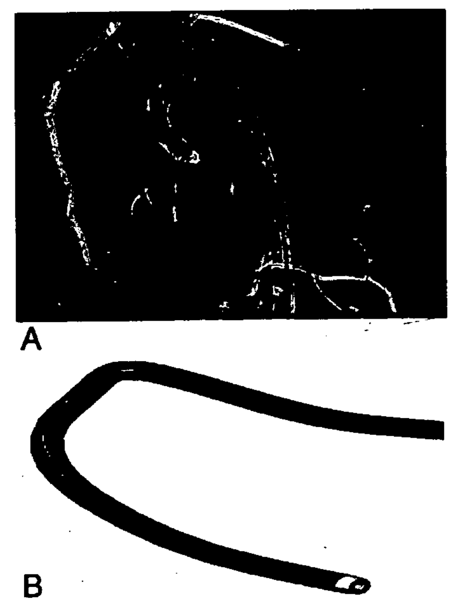

Figure 6. 3-D Navigation-based catheter design. (a) A virtual catheter is navigated to the aorta arch. (b) The catheter hook is constructed with proper configuration.

4. Catheter Validation

CathValidator, the third part of CathWorks, is an efficient tool to examine and evaluate the new design concept. The integration of the design process and validation process in a single environment is another unique feature of CathWorks. When a new design is done, users can immediately test the new design with the same platform.

4.1 Catheter Force-displacement Testing

The catheter head is the final taper or distal end of the device that is inserted into the patient's vessel at the very beginning of the catheterization procedure. Catheters have various curve shapes to increase maneuverability in the vasculature. Apart from the efficient calculation of the interaction between catheter and vascular wall, the tailored FEM engine developed in the system is also able to provide deformation simulation of the force-displacement at the distal head. Fig. 7 illustrates the user interface for this analysis. Users can apply force/torque to any of the nodes at the catheter's distal parts to analyze the displacement of shape with a variety of materials. An increment method is applied to obtain the deformation of the head part when

external force and/or torque are introduced. This test allows users to interactively change material properties to verify different catheter designs.

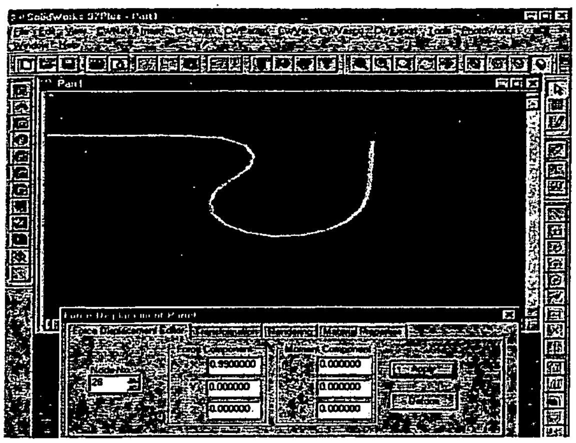

Figure 7. Force-displacement analysis.

4.2 Catheter Shape Flexibility Testing

Catheter shapes are usually designed corresponding to different catheterization functions or procedures. Flexibility of the catheter hook is an important characteristic for catheter navigation. From the elasticity theory, the energy sum of the slender catheter rods can be described as a function of the rod parameters of radius and twisting angles between neighboring rods with reference to the catheter's natural configuration using an arc-length representation [9]. The material property of each hook rod, (e.g. Young and Shears modulus) determines the flexibility of catheters. When the guide-wire interacts with the catheter (inside the lumen of the catheter), the two tubes tend to reach an energy equilibrium. This provides a good test for the interaction between catheter and guide-wire. The material properties of catheter and guide-wire are able to be interactively modified with a simple graphical user interface. Fig. 8 shows a MANI catheter (light) interacting with a guide-wire (dark): Fig. 8a gives the original configuration, and Figs. 8b-8d give the intermediate equilibrium positions due to the interaction between catheter and guide-wire when the guide-wire is inserted inside the catheter lumen.

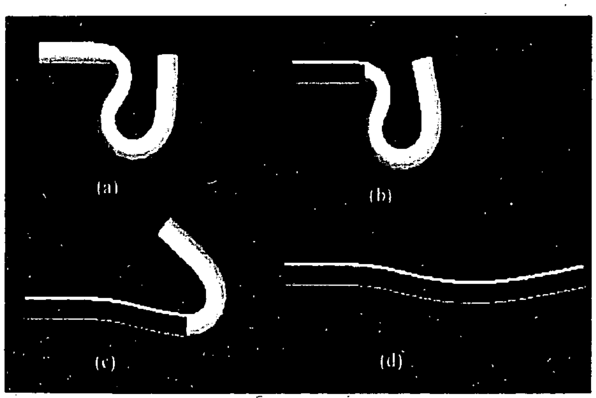

Figure 8. Interaction of catheter and guide-wire.

4.3 Catheter Navigability Testing

Catheter navigability or maneuverability is the ability to advance a catheter around sharp bends or through tortuous vascular segments. The computerized test of navigability is achieved by employing FEM analysis. A catheter as a slender structure is discretized into a flexible multibody system with a finite number of 3-D FEM beam elements. The blood vessels are assumed to be rigid circular tube-structures. This assumption is based on the observation that a majority of the great vessels have circular cross-sections and they are well stretched by the surrounding muscles. The catheter navigation is considered as a sequence of movements such as push, pull, and/or twist of the flexible multi-body system inside the rigid tube-structure. The movement of an element of the multi-body system at each step is assumed to consist of a rigid-body displacement and a relative deformation. We first move the elements of the system as rigid bodies by applying the multi-body dynamic method [6] at each step. The deformations at their equilibrium position are then obtained by applying the finite element method. Contact forces between the catheter and the walls of the vessels are introduced at the catheter nodes, which fall outside the vessels during the rigid moves, to push the catheter back into the tubes. Those contact forces, however, are functions of the position of the catheter at each time step and to compute them is very time consuming.

We have developed an efficient semi-implicit algorithm by using the hierarchy structure of the vasculature for computing the contact forces involved. The computation of contact force consists of two steps: 1) checking whether or not catheter nodes are outside the vessels; 2) calculating the contact force at the nodes if they are outside. In order to achieve an efficient inside/outside check, all the branch segments of the vasculature are linked through a hierarchical relation by specifying its parents and children. Each catheter node is associated with one branch segment and the inside/outside check for this node is conducted only with respect to its segment and parent-child segment group, rather than to compare with all the branch segments of the vasculature. This significantly speeds up the checking process. The contact force at the outside node is defined as $\mathbf{F} = cd\mathbf{N}$, where d is the distance between the node and the surface of the vessel, $\mathbf{N}$ is the unit vector pointing from the node to the surface along the distance direction, while c is the coefficient representing some physical characteristic parameters of the contact. It is currently set up with an arbitrary number since the flexibility of the vessels has not been taken into consideration in the present study.

5. Conclusion

We have been developing a prototyping system for catheter design, presentation, and verification. The advantage of such system lies in the CAD integration of design, validation, and presentation. Users are able to interactively prototype new devices based on a built-in vascular model using feature-based modelling and finite element methods.

With more and more vascular knowledge added to the system, CathWorks should be able to provide more intelligent assistance to the catheterization professionals for process planning or pre-treatment planning. 3-D reconstruction of vasculature is a challenging task. Modelling of complicated vascular tubular networks is one of our future projects. The current study is limited to the catheter and guide-wire device. More efforts will be contributed to the study of next generation catheterization devices such as stent-grafts.

Acknowledgement

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